UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

MARY MILLER and GENE MILLER,	)	**Civil Action No.: 3:17-cv-516**
Plaintiff,	)	
v.	)	**COMPLAINT AND JURY DEMAND**
JOHNSON & JOHNSON AND ETHICON, INC.	)	
Defendants.	)	

Come now Plaintiffs, Mary Miller and Gene Miller ("Plaintiffs"), by and through undersigned counsel, and bring this action against Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants"), and allege as follows:

1. Plaintiffs are, and were, at all relevant times, citizens and residents of Illinois and the United States.

2. Defendant Johnson & Johnson ("J&J") is a corporation incorporated in New Jersey, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Defendant J&J is a citizen of New Jersey.

3. Defendant J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing,

testing, training, distribution and sale of the hernia repair mesh products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc.

4. Defendant Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson. Defendant Ethicon, Inc. is a corporation incorporated in the State of New Jersey with its principal place of business in Somerville, New Jersey. Ethicon is a citizen of New Jersey.

5. Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including Physiomesh (hereinafter may be referred to as the "product").

6. J&J, directly and/or through the actions of Ethicon, Inc., has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Physiomesh.

7. Defendants are individually, jointly and severally liable to Plaintiffs for damages suffered by Plaintiffs' Mary Miller and Gene Miller arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective mesh products at issue in the instant action, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

8. Defendants are vicariously liable for the acts and/or omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

JURISDICTION AND VENUE

9. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiffs and all Defendants. The amount in controversy exceeds $75,000, exclusive of interests and costs.

10. This Court has personal jurisdiction over each of the Defendants pursuant to the Illinois Long-Arm Statute. Defendants transact business within the State of Illinois, and Defendants committed tortious acts and omissions in Illinois. Defendants' tortious acts and omissions caused injury to Plaintiffs in the State of Illinois. Defendants have purposefully engaged in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, medical devices including Physiomesh mesh products in Illinois, for which they derived significant and regular income. The Defendants reasonably expected that that their defective mesh products, including Physiomesh, would be sold and implanted in Illinois.

11. Defendant Ethicon is registered to transact business in Illinois, and is thus also subject to personal jurisdiction.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

FACTS COMMON TO ALL COUNTS

13. On April 23, 2012, Plaintiff Mary Miller was implanted with a Physiomesh (15CM x 20CM) product at St. Mary's Hospital - Centralia 400 N. Pleasant Ave., Centralia, IL 62801 to attempt Laproscopic repair of an Incisional hernia.

14. Defendants manufactured, sold, and/or distributed the Physiomesh device to Plaintiff Mary Miller, through her doctors, to be used for treatment of hernia repair.

15. On January 22, 2016, Plaintiff Mary Miller underwent surgery at Salem Township Hospital in Salem, IL for recurrent ventral abdominal wall hernia secondary to disruption of the previous placed mesh and mesh infection. The procedure consisted of laparoscopic complete removal of her previously placed Ethicon Physiomesh and lysis of intestinal adhesions due to mesh failure.

16. Since the implant surgery to present, Mrs. Miller has suffered severe abdominal pain and complications caused by the defective Physiomesh that was implanted in her.

17. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of Physiomesh, including providing the warnings and instructions concerning the product.

18. Among the intended purposes for which Defendants designed, manufactured and sold Physiomesh was use by surgeons for hernia repair surgeries, the purpose for which the Physiomesh was implanted in Plaintiff Mary Miller.

19. Defendants represented to Plaintiff Mary Miller and her physicians that Physiomesh was a safe and effective product for hernia repair.

20. Defendants' Physiomesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the Physiomesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; inadequate or failure of incorporation/ingrowth; migration; scarification; deformation of mesh; improper wound healing; excessive and chronic inflammation; adhesions to internal organs;

erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.

21. Physiomesh has a unique design incorporating five (5) distinct layers: two layers of polyglecaprone-25 ("Monocryl") film covering two underlying layers of polydioxanone film ("PDS"), which in turn coat a polypropylene mesh. This design is not used in any other hernia repair product sold in the United States. The multi-layer coating was represented and promoted by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the multi-layer coating prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction including migration and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing.

22. When affixed to the body's tissue, the impermeable multi-layer coating of the Physiomesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection, abscess formation and other complications.

23. The multi-layer coating provides a breeding ground for bacteria in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

24. The multi-layer coating of Defendants' Physiomesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

25. Defendants knew or should have known of the cytotoxic and immunogenic properties of the multi-layer coating of the Physiomesh prior to introducing it into the stream of commerce.

26. The polypropylene mesh portion of the Physiomesh was insufficient to withstand normal abdominal forces, which resulted in recurrent hernia formation and/or rupture and deformation of the mesh itself.

27. When the multi-layer coating of the Physiomesh is disrupted and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause damage to organs, and potentiate fistula formation.

28. These manufacturing and design defects associated with the Physiomesh were directly and proximately related to the injuries suffered by Plaintiff Mary Miller.

29. Neither Plaintiff Mary Miller nor her implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of Physiomesh. Moreover, neither Plaintiff Mary Miller nor her implanting physician were adequately warned or informed by Defendants of the risks associated with the Physiomesh or the frequency, severity, or duration of such risks.

30. The Physiomesh implanted in Plaintiff Mary Miller failed to reasonably perform as intended. The mesh failed, caused serious injury, and necessitated several follow-up surgeries to repair the damage including invasive surgeries to repair the hernia that the Physiomesh was initially implanted to treat.

31. Plaintiff Mary Miller's severe adverse reaction, and the necessity for surgical intervention because of the Physiomesh, directly and proximately resulted from the defective and dangerous condition of the product and Defendants' defective and inadequate warnings about the

risks associated with the product, and the frequency, severity and duration of such risks. Plaintiff Mary Miller has suffered, and will continue to suffer, both physical injury and pain and mental anguish, permanent and severe scarring and disfigurement, and has incurred substantial medical bills and other expenses, resulting from the defective and dangerous condition of the product and from Defendants' defective and inadequate warnings about the risks associated with the product.

FIRST CAUSE OF ACTION
Strict Product Liability: Defective Design

32. Plaintiffs re-alleges and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

33. At the time the Physiomesh that was implanted in Plaintiff Mary Miller's body, the product was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

34. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff Mary Miller in the condition in which the product was sold.

35. The implantation of Physiomesh in Plaintiff Mary Miller's body was medically reasonable, and was a type of use that Defendants intended and foresaw when it designed, manufactured and sold the product.

36. The risks of the Physiomesh design significantly outweigh any benefits that Defendants contend could be associated with the product's design. The multi-layer coating, which is not used in any other hernia mesh product sold in the United States, prevents tissue from incorporating into the mesh, leading to encapsulation, deformation, scarification and contraction,

migration, erosion and rejection. The impermeable multi-layer coating leads to seroma formation, and provides a breeding ground for infection, and protects bacteria from being eliminated by the body's natural immune response.

37. The multi-layer coating of the Physiomesh, which was marketed, promoted and intended as a barrier against adhesion to the internal organs, was only temporary; it was expected and intended to degrade over time inside the body. Thus, this coating prevented tissue in growth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh exposed to the internal viscera and tissues. The degradation of this multi-layer coating caused or exacerbated an intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the multi-layer coating (to prevent adhesion to the internal viscera and organs) was non-existent; the product provided no benefit while substantially increasing the risks to the patient.

38. The polypropylene mesh within the defective multi-layer coating of the Physiomesh was in itself dangerous and defective, particularly when used in the manner intended by Defendants in the Physiomesh. When implanted adjacent to the intestines and other internal organs, as Defendants intended for Physiomesh, polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

39. The polypropylene mesh used in the Physiomesh device was insufficient in strength to withstand the internal forces of the abdomen after implantation, which made the device susceptible to rupture and/or deformation, as occurred with the Physiomesh implanted in Mrs. Miller.

40. The appropriate treatment for complications associated with Physiomesh involves additional invasive surgery, and additional mesh being place. Thus eliminating any purported benefit that the mesh was intended to provide to the patient.

41. Physiomesh was designed and intended for intraperitoneal implantation, which involved the product being implanted in contact with the intestines and/or other internal organs, which unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

42. At the time the Physiomesh was implanted in Plaintiff Mary Miller, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries she suffered.

43. The Physiomesh product cost significantly more than competitive products because of its unique multi-layer coating, even though the multi-layer coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.

44. The Physiomesh implanted in Plaintiff Mary Miller failed to reasonably perform as intended, necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus provided no benefit to her.

45. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff Miller suffered injuries and damages as summarized herein.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SECOND CAUSE OF ACTION
Strict Product Liability: Failure to Warn

46. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

47. At the time the Physiomesh that was implanted in Plaintiff Mary Miller's body, the warnings and instructions provided by Defendants for the Physiomesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

48. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff Mary Miller in the condition in which the product was sold.

49. Plaintiff Mary Miller and her physicians were unaware of the defects and dangers of Physiomesh, and were unaware of the frequency, severity and duration of the defects and risks associated with the Physiomesh.

50. The Defendants' Instructions for Use provided with the Physiomesh expressly understates and misstates the risks known to be associated specifically with the Physiomesh by stating that "Potential adverse reactions are those typically associated with surgically implantable materials." No other surgical mesh sold in the United States – and no other "surgically implantable material" – suffers the same serious design flaws as Physiomesh. No other device or material contains the dangerous and defective multi-layer coating, which itself causes or increases the risks of numerous complications, including prevention of incorporation, increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory

reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Physiomesh.

51. The Defendants' Instructions for Use for the Physiomesh failed to adequately warn Plaintiff Mary Miller's physicians of numerous risks which Defendants knew or should have known were associated with the Physiomesh, including the risks of the product's inhibition of tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, intestinal obstruction, failure of repair/hernia recurrence, hernia incarceration or strangulation, or rupture of the mesh.

52. Defendants failed to adequately train or warn Plaintiff Mary Miller or her physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

53. Defendants failed to adequately warn Plaintiff Mary Miller or her physicians that necessary surgical intervention would necessitate further medical treatment to attempt to repair the same hernia that the failed Physiomesh was intended to treat.

54. Defendants represented to physicians, including Plaintiff Mary Miller's physician, that the multi-layer coating would prevent or reduce adhesion, and expressly intended for the Physiomesh to be implanted in contact with the intestines and internal organs and marketed and promoted the product for said purpose. Defendants failed to warn physicians that the multi-layer coating prevented tissue ingrowth, which is the desired biologic response to an implantable mesh device. Defendants failed to warn physicians that the multi-layer coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene would become adhered to the organs or tissue.

55. With respect to the complications that were listed in the Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with Physiomesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

56. If Plaintiff Mary Miller and/or her physicians had been properly warned of the defects and dangers of Physiomesh, and of the frequency, severity and duration of the risks associated with the Physiomesh, Plaintiff Mary Miller would not have consented to allow the Physiomesh to be implanted in her body, and Plaintiff Mary Miller's physicians would not have implanted the Physiomesh in Plaintiff Mary Miller.

57. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff Mary Miller suffered injuries and damages as summarized herein.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

THIRD CAUSE OF ACTION
Negligence

58. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

59. Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and warnings for Physiomesh, but failed to do so.

60. Defendants knew, or in the exercise of reasonable care should have known, that Physiomesh was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients in whom Physiomesh was implanted. Defendants knew or should have known that Plaintiff Mary Miller and her physicians were unaware of the dangers and defects inherent in the Physiomesh.

61. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing written instructions and warnings for Physiomesh, Plaintiff Mary Miller suffered injuries and damages as summarized herein.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

FOURTH CAUSE OF ACTION
Strict Products Liability Due to Non-Conformance with Representations

62. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

63. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff Mary Miller, and the public, that Physiomesh had not been adequately tested and found to be safe and effective for the treatment of hernia or soft tissue repair. The representations made by Defendants, in fact, were false.

64. Defendants' material representations concerning the Physiomesh while they were involved in their manufacture, sale, testing, quality, assurance, quality control, and distribution in

interstate commerce, were justifiably relied on by Plaintiff Mary Miller. Defendants materially misrepresented the Physiomesh high risk of unreasonable and dangerous adverse side effects.

65. Defendants materially misrepresented that the Defendants' Physiomesh have no serious side effects different from older generations of similar products and/or procedures to Plaintiff Mary Miller, her physicians, and the medical and healthcare community.

66. As a foreseeable, direct and proximate result of the misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Physiomesh had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, loss of life's enjoyment, remedial surgeries to remove the product, and other severe and personal injuries, which are permanent and lasting in nature.

67. As a direct and proximate result of the Defendants' conduct, Plaintiff Mary Miller has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

FIFTH CAUSE OF ACTION
Breach of Express Warranty

68. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same

be necessary, allege as follows:

69. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Physiomesh.

70. At all relevant times, Defendants intended that the Defendants' Physiomesh be used in the manner than Plaintiff Mary Miller in fact used them and Defendants expressly warranted that each Physiomesh and its component parts was safe and fit for use by consumers, that it was merchantable quality, that is side effects were minimal and comparable to other hernia mesh, and that it was adequately tested and fit for its intended use.

71. At all relevant times, Defendants were aware that consumers, including Plaintiff Mary Miller, would use the Physiomesh; which is to say that Plaintiff Mary Miller was a foreseeable user of the Defendants' Physiomesh.

72. Plaintiff Mary Miller and/or her implanting physician were at all relevant times in privity with Defendants.

73. The Defendants Physiomesh was expected to reach and did in fact reach consumers, including Plaintiff Mary Miller and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

74. Defendants breached various express warranties with respect to the Physiomesh including the following particulars:

A. Defendants represented to Plaintiff Mary Miller and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Physiomesh was safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Physiomesh;

B. Defendants represented to Plaintiff Mary Miller and her physicians and healthcare providers that the Defendants' Physiomesh was safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that Physiomesh was not safer than alternatives available on the market; and

C. Defendants represented to Plaintiff Mary Miller and her physicians and healthcare providers that the Defendants' Physiomesh was more efficacious than other alternative procedures and/or devices, and fraudulently concealed information, regarding the true efficacy of the Physiomesh.

75. In reliance upon Defendants' express warranty, Plaintiff Mary Miller individually and/or by and through her physician, was implanted with the Defendants' Physiomesh as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

76. At the time of making such express warranties, Defendants knew or should have known that the Defendants' Physiomesh did not conform to these express representations because the defendants' Physiomesh was not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendant's Physiomesh unreasonably unsafe for their intended purpose.

77. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff Mary Miller and the Public relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Defendants' Physiomesh.

78. Defendants breached their express warranties to Plaintiff Mary Miller in that the Defendants' Physiomesh was not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

79. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff Mary Miller was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SIXTH CAUSE OF ACTION
Breach of Implied Warranty

80. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

81. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Physiomesh.

82. At all relevant times, Defendants intended that the Defendants' Physiomesh be implanted for the purposes and in the manner that Plaintiff Mary Miller or her implanting physicians in fact used them and Defendants impliedly warranted each Physiomesh and its component parts to be of merchantable quality, safe and fit for such use, and was not adequately tested.

83. Defendants were aware that consumers, including Plaintiff Mary Miller or her physicians, would implant the Defendants' Physiomesh in the manner directed by the instructions for use; which is to say that Plaintiff Mary Miller was a foreseeable user of the Defendants' Physiomesh.

84. Plaintiff Mary Miller and/or her physicians were at all relevant times in privity with Defendants.

85. The Defendants' Physiomesh was expected to reach and did in fact reach consumers, including Plaintiff Mary Miller or her physicians, without substantial change in the condition in which they were manufactured and sold by Defendants.

86. Defendants breached various implied warranties with respect to the Physiomesh including the following particulars:

A. Defendants represented to Plaintiff Mary Miller and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Physiomesh was safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Physiomesh;

B. Defendants represented to Plaintiff Mary Miller and her physicians and healthcare providers that the Defendants' Physiomesh was safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Physiomesh was not safer than alternatives available on the market; and

C. Defendants represented to Plaintiff Mary Miller and her physicians and healthcare providers that the Defendants' Physiomesh was more efficacious than other alternative procedures and/or devices, and fraudulently concealed information, regarding the true efficacy of the Physiomesh.

87. In reliance upon Defendants' implied warranty, Plaintiff Mary Miller individually and/or by and through her physician, used Physiomesh as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

88. Defendants breached their implied warranty to Plaintiff Mary Miller in that the Defendants' Physiomesh was not merchantable quality, safe and fit for their intended use, or adequately tested.

89. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff Mary Miller was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SEVENTH CAUSE OF ACTION
Negligent Misrepresentation

90. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

91. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff Mary Miller, and the public, that Physiomesh had not been

adequately tested and found to be safe and effective for the treatment of hernia or soft tissue repair. The representations made by Defendants, in fact, were false.

92. Defendants failed to exercise ordinary care in the representations concerning the Physiomesh while they were involved in their manufacture, sale, testing, quality, assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented Physiomesh's high risk of unreasonable and dangerous adverse side effects.

93. Defendants breached their duty in representing that the Defendants' Physiomesh have no serious side effects different from older generations of similar products and/or procedures to Plaintiff Mary Miller, her physicians, and the medical and healthcare community.

94. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Physiomesh had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, loss of life's enjoyment, remedial surgeries to remove the product, and other severe and personal injuries, which are permanent and lasting in nature.

95. As a direct and proximate result of the Defendants' conduct, Plaintiff Mary Miller has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

EIGHTH CAUSE OF ACTION
Fraud

96. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

97. At all relevant times, Defendants' marketed, promoted, and/or sold Physiomesh as safe, efficacious, and suitable for human implantation.

98. Physiomesh is not safe, efficacious, or suitable for human implantation.

99. The Defendants' marketed, promoted, and/or sold Physiomesh as safe, efficacious, and suitable for human implantation with the intent that more patients and physicians would utilize the Physiomesh, increasing the Defendants' profits.

100. Plaintiff Mary Miller and her physician utilized the Physiomesh because they believed Physiomesh was safe, efficacious, and suitable for human implantation at the time, because the Defendant's deceptively marketed, promoted, and/or sold Physiomesh as such.

101. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed Physiomesh, and up to the present, knew and willfully deceived Plaintiff Mary Miller, the FDA, Plaintiff Mary Miller's physician, the medical community, and the general public, as to the true facts concerning Physiomesh, which the Defendants had a duty to disclose.

102. Defendants are the sole bearer of the true, accurate, unaltered information, test, studies, trials, and data on the safety, efficacy, and suitable for human implantation of Physiomesh, and therefore the Plaintiff Mary Miller and her doctor had no reason or information to believe that the Defendants claims were in fact false.

103. The Plaintiff Mary Miller and her physician intended to select a safe and efficacious mesh for hernia and/or soft tissue repair that was suitable for human implantation, and selected the Defendants' Physiomesh because of the false claims that the Defendants made about the safety, efficacy and suitability of Physiomesh for hernia and/or soft tissue repair as used by the Plaintiff Mary Miller and her physician.

104. Defendants are the sole bearer of the true, accurate, unaltered information, test, studies, trials, and data on the safety, efficacy, and suitable for human implantation of Physiomesh, and therefore Plaintiff Mary Miller and her physician had no other option but to rely of the Defendants' representations.

105. As a direct and proximate result of Plaintiff Mary Miller and/or her physicians' reliance on the Defendants' misrepresentations, Plaintiff Mary Miller has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

NINTH CAUSE OF ACTION
Unjust Enrichment

106. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

107. Defendants are and at all times were the manufacturers, sellers, and/or suppliers of the Defendants' Physiomesh.

108. Plaintiff Mary Miller paid for the Defendants' Physiomesh for the purpose of treatment for hernia repair and/or a soft tissue injury or other similar condition.

109. Defendants have accepted payment by Plaintiff Mary Miller and others on Plaintiff Mary Miller's behalf for the purchase of the Defendants' Physiomesh.

110. Plaintiff Mary Miller has not received the safe and effective medical device for which she paid.

111. It would be inequitable for Defendants to keep this money, because Plaintiff Mary Miller did not in fact receive a safe and effective medical device.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

TENTH CAUSE OF ACTION
Violation of Unfair and Deceptive Trade Practices Acts
(Consumer Protection Laws)

112. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

113. Plaintiff Mary Miller purchased and used the Defendants' Physiomesh primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

114. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff Mary Miller would not have purchased and/or paid for the Defendants' Physiomesh, and would not have incurred related medical cost and injury.

115. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, money from Plaintiff Mary Miller for Physiomesh that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

116. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

A. Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have.

B. Advertising goods or services with the intent not to sell them as advertised; and,

C. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

117. Plaintiff Mary Miller was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' Physiomesh. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Physiomesh.

118. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Physiomesh.

119. Had Defendants not engaged in the deceptive conduct described above, Plaintiff Mary Miller would not have purchases and/or paid for Physiomesh, and would not have incurred related medical cost.

120. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff Mary Miller, constituted

unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

121. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of stateconsumer protection statues, as listed below.

122. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations.

a) 815 Ill. Comp. Stat. Ann. §§ 505/1 *et seq.* (Consumer Fraud and Deceptive Business Practices Act); and

b) 815 Ill. Comp. Stat. Ann. §§ 510/1 *et seq.* (Uniform Deceptive Trade Practices Act).

123. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

124. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' Physiomesh was fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

125. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair,

deceptive, fraudulent and unconscionable trade and business practices and false advertising.

126. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Physiomesh and failed to take any action to cure such defective and dangerous conditions.

127. Plaintiff Mary Miller and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

128. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

129. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff Mary Miller has suffered ascertainable losses and damages

130. As a direct and proximate result of Defendants' violations of the states; consumer protection laws, Plaintiff Mary Miller has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of profits, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems just and proper.

ELEVENTH CAUSE OF ACTION
Gross Negligence

131. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint

as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

132. The wrongs done by defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff Mary Miller for which the law would allow, and which Plaintiff Mary Miller will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff Mary Miller; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff Mary Miller.

133. Plaintiff Mary Miller relied on the representation and suffered injury as a proximate result of this reliance.

134. Plaintiff Mary Miller therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

135. Plaintiff Mary Miller also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff Mary Miller. In that regard, Plaintiff Mary Miller will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

TWELFTH CAUSE OF ACTION
Negligent Infliction of Emotional Distress

136. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

137. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' Physiomesh to Plaintiff Mary Miller.

138. Defendants carelessly and negligently concealed the harmful effects of the Defendants' Physiomesh from Plaintiff Mary Miller individually and/or her physician on multiple occasions and continue to do so to this day.

139. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of Physiomesh to Plaintiff Mary Miller individually and/or her physician on multiple occasions and continue to do so to this day.

140. Plaintiff Mary Miller was directly impacted by Defendants' carelessness and negligence, in that Plaintiff Mary Miller has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase Physiomesh sold and distributed by Defendants.

141. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of Physiomesh to Plaintiff Mary Miller individually and/or her physician after Plaintiff Mary Miller sustained emotional distress, severe physical injuries, and

economic loss.

142. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of Physiomesh to Plaintiff Mary Miller individually and/or her physician knowing that doing so would cause the Plaintiff Mary Miller to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

143. As a proximate result of the Defendants' conduct, Plaintiff Mary Miller has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, cost of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

THIRTEENTH CAUSE OF ACTION
Loss of Consortium

144. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

145. At all times relevant herein, Plaintiff, Gene Miller, was married to and residing with his wife, Mary Miller.

146. As a direct and proximate result of the above and foregoing strict liability claims against the Defendants which directly and proximately caused severe, permanent and lasting personal injuries and disabilities to be suffered by Mary Miller, Plaintiff, Gene Miller, has in the past and will in the future be deprived of the services, companionship, society, affection and other related benefits of marriage due to the injuries and disabilities caused to his spouse, Mary Miller.

147. As a direct and proximate result of the above and foregoing strict liability claims of the Defendant, Plaintiff, Mary Miller, has been damaged due to his loss of consortium.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

FOURTEENTH CAUSE OF ACTION
Willful and Wanton Conduct – Punitive/Exemplary damages

148. Plaintiff Mary Miller hereby incorporates by reference all allegations contained in the preceding paragraphs, as though fully set forth herein.

149. Defendants failed to adequately test and study the Physiomesh to determine and ensure that the product was safe and effective prior to releasing the product for sale for permanent human implantation, and Defendants continued to manufacture and sell Physiomesh after obtaining knowledge and information that the product was defective and unreasonably unsafe. Even though Defendants has other hernia repair mesh devices that do not present the same risks as the Physiomesh, Defendants developed, designed and sold Physiomesh, and continue to do so, because the Physiomesh has a significantly higher profit margin than other hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective Physiomesh, including the risk of failure and serious injury, such as suffered by Plaintiff Mary Miller. Defendants willfully and recklessly failed to avoid those consequences, and in doing so, Defendants acted intentionally, maliciously and recklessly with regard the safety of those persons who might foreseeably have been harmed by the Physiomesh product, including Plaintiff Mary Miller, justifying the imposition of punitive damages.

PRESERVATION CLAIMS

150. Plaintiffs hereby incorporate by reference all allegations contained in the preceding paragraphs, as though fully set forth herein.

151. Many States have recently enacted tort reform statutes with "exclusive remedy" provisions. courts have yet to determine whether these exclusive remedy provisions eliminate or supersede, to any extent, state common law claims. If during the pendency of this action this court makes any such determination, Plaintiffs hereby specifically make claims to and preserves any State claim based upon any exclusive remedy provision, under any state law this court may apply, to the extent not already alleged above.

152. To the extent that Defendant(s) may claim that one or more of Plaintiffs' claims are barred by the applicable statute of limitations, Plaintiffs asserts that the statute of limitations is and has been tolled by Plaintiffs' discovery that her injury(ies) was/were caused by Defendants' defective product and failure to properly and adequately warn of the products' risks, all as more fully set forth in this Complaint, after the injury sustained by Plaintiffs.

Prayer for Relief

WHEREFORE, the acts and omissions of Defendants, as set forth above, are the result of negligence and willful and malicious or fraudulent conduct, or conduct that manifests a knowing and reckless indifference toward, and a disregard of, the rights of others, including Plaintiffs. The Defendants continue to engage in such behavior against other individuals and such engagement further aggravates Plaintiffs' damages, which further aggravation is known, or should be known to Defendants. As a direct and proximate result of Defendants' action and/or inaction, Plaintiffs have suffered and will suffer the following damages:

A. Compensatory damages in excess of $75,000, exclusive of interest and costs;

B. Plaintiffs' past lost wages and loss of earning capacity;

C. Costs of suit;

D. General and non-economic damages;

E. Punitive/Exemplary damages;

F. Pre-judgment and post-judgment interest; and

G. Such other relief as this Court deems just and proper under the circumstances.

Plaintiff demands judgment in her favor and seeks relief against Defendants.

Jury Demand

Plaintiff demands a trial by jury on all issues so triable.

Respectfully submitted,

/s/ Richard W. Schulte
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